

REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claims 1, 2, 4-27, and 29-31 were pending in this application. Claim 1 has been amended; claims 20 and 29-31 have been cancelled. New claims 32 and 33 have been added. These amendments are made without prejudice or disclaimer and do not include any new matter. Applicants reserve the right to prosecute any unclaimed or cancelled subject matter in this or another application as appropriate. Consideration and entry of this amendment is respectfully requested.

REJECTIONS UNDER 35 U.S.C. 103(a)

A. Claims 1, 2, 4-17 and 20

Claims 1-2, 4-17 and 20 stand rejected under 35 U.S.C. 103(a) over Hurpin (1998) in view of Hodge (1997), Rice (US Pat. No. 6,127,116; 1997), and Lehner (1999). Applicants respectfully traverse these rejections as indicated below.

Hurpin is alleged to demonstrate that administration of antigen to a lymphatic tissue may be a successful route of administration. As Hurpin does not teach a prime-boost regimen, Hodge is cited as teaching the use of two different poxviral vectors to generate an immune response. As neither of these references teaches direct intranodal administration of antigen, both Rice and Lehner are cited. Rice is alleged to teach direct intranodal administration as a preferred immunization route. Lehner is alleged to provide a reasonable expectation of success in using intranodal immunization by demonstrating success using their "targeted iliac lymph node" or "TILN" technique. As described below, the Applicants do not believe this combination of references renders the instantly claimed method obvious.

As amended, the claims relate only to administration of antigen directly to a lymph node. Hurpin is completely silent as to administration of an antigen directly into a lymph node and related only to immunization via the intravenous, subcutaneous, intradermal, intramuscular, and intrasplenic routes. Hodge is not alleged to suggest or demonstrate intranodal immunization but merely as a demonstration of a successful prime-boost protocol. Applicants respectfully disagree that either Lehner or Rice supplement the deficiencies of Hurpin and Hodge.

Applicants maintain that Rice merely mentions at col. 43, lines 43-52 that the cDNAs described therein may be incorporated into vaccines that may be administered “directly...to lymphoid tissues, e.g., lymph nodes....” Applicants are aware that the Rice reference is being cited along with the Lehner reference. However, it must be pointed out that Rice’s suggestion provides insufficient support for an obviousness rejection. As recently emphasized by the Federal Circuit (PharmaStem Therapeutics, Inc. v. Viacell, Inc. 491 F.3d 1342, 1364 (Fed. Cir., 2007)):

... an invention would not be deemed obvious if all that was suggested “was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”

Rice does nothing more than point out a particular form of vaccine and provides absolutely no guidance whatsoever as to how to achieve it.

Lehner does not cure the deficiencies of Huprin, Hodge, and Rice. Applicants have previously pointed out, Lehner teaches “a subcutaneous immunization technique, which aims to administer the vaccine in the proximity of the internal and external iliac lymph nodes....” (Lehner, p. S489, col. 2). Applicants maintain that, in fact, neither the steps of the “TILN” method nor the meaning of “in the proximity of” are clear from the reference. Lehner points to citation 12 (Lehner, et al. Nature Medicine, Vol. 2, No. 7, pp. 767-775, July 1996) as apparently providing the details of the “subcutaneous TILN route”. The 1996 paper, in turn, points to its citation 30 (Lehner, et al. J. Immunol. 153: 1858-1868 (1994)). The 1994 paper states on p. 1859, col. 2, first full paragraph, that the monkeys were administered the antigen “by targeted s.c. injection into the site defined below.” The “site defined below” appears to be defined on p. 1860, second column, fourth full paragraph, as:

The localization of the iliac lymph nodes was studied in five autopsies by s.c. injection of 0.5 ml of India ink, aimed to be deposited in the proximity of the internal iliac lymph nodes before the autopsy. The internal iliac lymph nodes were found distal to the femoral vessels and about 2 to 4 cm s.c.

Applicants have not identified any further description of the method. Lehner merely alleged that the technique deposited antigen "in the proximity of" lymph nodes which, according to the 1994 Lehner reference, is "about 2 to 4 cm" from the closest lymph node. Applicants maintain that depositing antigen "about 2 to 4 cm" from a lymph node does not provide any reasonable expectation of success in administering antigen directly to a lymph node. And, as Applicants' have previously argued and presently maintain, the control subcutaneous administration experiment presented in their Example 1 is similar to the Lehner subcutaneous technique said to administer the vaccine "in the proximity of" lymph nodes. Applicants' claimed administration "directly into a lymph node" resulted in an immune response much greater than that produced by the subcutaneous method (e.g., Fig. 5).

Applicants respectfully maintain that the combination of Hurpin, Hodge, Rice and Lehner cannot support a proper prima facie showing of obviousness. Neither Hurpin nor Hodge demonstrate direct administration to a lymph node. Rice merely mentions it as a possibility. And Lehner's administration of antigen "in the proximity of" lymph nodes would not be understood to be reasonably predictive of success in administering directly to a lymph node. For these reasons, the Applicants respectfully disagree with the Examiner's conclusions that the claimed invention was obvious in view of the cited art. Accordingly, it is respectfully requested that these rejections be withdrawn.

B. Claims 18-19

Claims 18 and 19 stand rejected under 35 U.S.C. 103(a) over Hurpin (1998) in view of Hodge (1997), Rice (US Pat. No. 6,127,116; 1997), and Lehner (1999) as applied to claims 1-2, 4-17 and 20 and further in view of Zaremba (1997) and Salgaller (1996). Applicants respectfully traverse these rejections as indicated below.

Applicants have discussed the deficiencies of the Hurpin, Hodge, Rice and Lehner references above. As described therein, Applicants do not believe that Hurpin, Hodge, Rice and Lehner provide any reasonable expectation of success in carrying out the claimed methods. Regarding dependent claims 18 and 19, Applicants do not believe Zaremba and / or Salgaller satisfy the deficiencies of Hurpin, Hodge, Rice and Lehner. Accordingly, it is respectfully requested that these rejections be withdrawn.

C. Claims 21-27

Claims 21-27 stand rejected under 35 U.S.C. 103(a) over Hurpin (1998) in view of Hodge (1997), Rice (US Pat. No. 6,127,116; 1997), and Lehner (1999) as applied to claims 1-2, 4-17 and 20 and further in view of Barnett (1997). Claim 31 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully traverse the remaining rejections as indicated below.

Applicants have discussed the deficiencies of the Hurpin, Hodge, Rice and Lehner references above. As described therein, Applicants do not believe that Hurpin, Hodge, Rice and Lehner provide any reasonable expectation of success in carrying out the claimed methods. Regarding dependent claims 21-27, Applicants do not believe Barnett satisfies the deficiencies of Hurpin, Hodge, Rice and Lehner. Accordingly, it is respectfully requested that these rejections be withdrawn.

CONCLUSIONS

Consideration and entry of this response is respectfully requested. Applicants believe the claims are now in condition for allowance, and respectfully request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the undersigned if it is believed doing so would assist in the examination of this application.

Date: November 19, 2008

/Patrick J. Halloran/

Patrick J. Halloran

Reg. No. 41, 053

Patrick J. Halloran, Ph.D., J.D.
3141 Muirfield Road
Center Valley, PA 18034
Tel: 610-984-4751
Fax: 484-214-0164
e-mail: pat@pathalloran.com